

**REMARKS/ARGUMENTS**

As an initial matter, Applicants wish to express their gratitude for the Examiner's time and valuable comments during our recent in person interview of 13 October 2005. During the interview of 13 October 2005, Applicants explained the details of the present application and discussed possible claim limitations to further distinguish the prior art. In particular, Applicants described the irregular nature of the transducer surface which results in an annular focal region.

Claims 1-12 were examined. Claims 1-8 and 11 have been amended. Claims 9 and 10 are canceled. Reexamination and reconsideration of the claims are respectfully requested.

Examiner has generously provided valuable consideration into possible claim language to better describe the present invention. Applicants have attempted to incorporate those comments in the amended claims. In response to examiner's comments during the interview of 13 October of this year, Applicants have amended the claims to incorporate the axial offset in the edge of the transducer shown in the various figures of the application, in particular Figs. 3, 5 and 6a-g.

**Rejections Under 35 USC 102.** In the first paragraph of the office action dated June 23, 2005, the examiner states that Levin teaches a vortex transducer. Applicants maintain that the structure illustrated in Levin was a distal tip of an energy horn. The horn was not a transducer. The horn tip was identified as having an irregular shape, but since the tip element in Levin is not a transducer, Levin fails to teach all elements of the present application in a single reference, Levin does not anticipate the subject matter of the present application. Examiner has orally agreed to withdraw the Levin reference, and cancel the pending rejection.

Applicants respectfully disagrees. Levin channels ultrasound energy through a catheter like device. Levin does not disclose or describe anything other than a generic "ultrasonic energy source." For instance, Examiner cites Col. 6, Lines 9-12 as "explicitly disclose transducer." With respect, Examiner has taken the passage out of context. The full passage beginning at Col. 6, line 6 describes the device of Levin, and that the device is "...constructed to be coupled to a source of ultrasound energy (not shown)." Thus only a source of ultrasound energy is disclosed, however no transducer as far as shape, function, or any other parameter

relevant to the construction of a transducer is disclosed. (It may be of interest to note, that the word “transducer” only appears in Levin three times, and all three in reference to the attachment of an energy source at the proximal end).

In the third paragraph Examiner states “Levin et al disclose a system for producing vortex ultrasound focal field comprising a mechanically formed ultrasound transducer that has irregular shape to produce mechanical vortex where the ultrasound transmission achieves focusing on treatment.” Page 3, paragraph 3, Office action dated June 23, 2005.

Applicants respectfully disagree. The phrase “vortex ultrasound” does not appear anywhere in Levin. Once again since the Levin reference fails to teach the element described in the claims of the present application, the reference does not satisfy the 35 USC 102 requirement.

Furthermore, Levin does not describe the shape of the ultrasound transducer. Examiner’s assertion that Levin teaches a “transducer that has irregular shape” is inaccurate. Examiner cites Fig. 49A of Levin, and Col. 7, lines 1-17, and Col. 25, lines 1-12. Applicants address each in turn.

The element shown in Fig. 49A of Levin does indeed have an irregular shape. However the shape disclosed is for the catheter tip, not a transducer. Since the element shown in Fig. 49A is not a transducer, the irregular shape not related to the generation of a focal field in Levin. Levin states “FIGS. 49A and 49B depict another embodiment of a distal tip...” Levin at Col. 16, lines 23-24. Levin very clearly teaches that the transducer is at the proximal end with references to numerous to list. Therefore the irregular shape of the tip in Fig. 49A IS NOT a “transducer that has irregular shape.”

In Col. 7, lines 1-17, Levin discusses standing wave patterns. Levin teaches “the ultrasonic wavelength is a function of the shape, dimensions and material of the horn and probe.” Id. At lines 3-4. The discussion of Levin here refers to two non transducer elements. The “horn” is connected to the ultrasound energy source. “...it will be understood that the means of coupling the proximal end of the horn to an ultrasound energy source...” Levin Col. 7, lines 18-20. The “probe” is formed from a tapered member of the horn and is distal to the ultrasound energy source. Levin Col. 6, lines 1-5, and Fig. 1. Therefore Examiner’s assertion that Col. 7, lines 1-17 of Levine support a “transducer that has irregular shape” is also incorrect.

Examiner has also asserted that Col. 25, lines 1-12 support the idea that Levine teaches a “transducer that has irregular shape to produce mechanical vortex.” Applicants once again respectfully disagree. First mechanical vortex is not relevant to the present disclosure. The present disclosure does not teach producing a mechanical vortex, but an annular focal field, which has become known in the field as a “vortex transducer.” Second Examiner has misstated Levin in this passage. Levin teaches that a vortex can be formed while withdrawing the tip. Specifically Levin teaches a means of breaking up thrombus (blood clots). “One means of attenuating the thrombus strands is to advance the tip in a stepwise motion through the thrombus while the tip is oscillating in a longitudinal direction. This action effectively pulls apart or mechanically disorganizes the blockage by utilizing a vortex to suck the blockage toward the tip *as the tip is being withdrawn.*” Levin Col. 25, lines 5-11 (emphasis added).

Thus the creation of a vortex in Levin is through a mechanical operation of advancing and withdrawing the catheter to create a vacuum. There is no such similar teaching in Applicant’s disclosure. There is no similarity to the “Vortex Transducer” of Applicant’s disclosure and the teaching of Levin. Since Levin fails to teach the transducer of Applicant’s disclosure, Levin fails to teach all elements of the claimed subject matter, in the same arrangement and for performing the same function. Applicants believe Levin cannot anticipate the present disclosure under 35 USC 102, and Applicants respectfully request the rejection be withdrawn.

**Rejections Under 35 USC 103(a)** Examiner has rejected claims 2-6 as unpatentable over Levin as applied to claim 1, and further in view of Dias et al (US 5,400,788) in the Office Action dated 23 June 2005.

Examiner similarly rejects claims 7-9, 11 and 12 as being unpatentable over Levin et al, in view of Dias et al.

Applicants herein amend claim 7 and 8 to depend from amended claim 1. Claims 9 and 10 are cancelled. Claim 11 is now amended and claim 12 now depends from amended claim 11.

Applicants have cancelled claims 9 and 10, rendering the rejections based on Levin et al, in view of Dias et al, moot.

Levin shows at Fig. 49A a distal tip section, with a generic "ultrasound energy source" at the proximal end. Examiner has not demonstrated any motivation to combine the two references, namely why would it be obvious to combine the Dias transducer with the Levin distal tip (a non-transducer). Even if the two were combined, the result would render each of the individual inventions inoperable. If Dias adopted an irregular shape for his transducer, he would not produce a focal point, and the ultrasound energy would not be suitable for carrying down the propagation wave guide. The Dias disclosure would be completely inoperable.

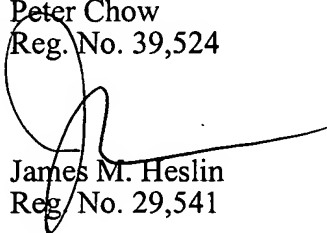
If Levin incorporated Dias, the segmented tip would not function as intended, since the segmented filler material and different material elements of the distal tip would likely cause chaos for the ultrasound energy propagating down the horn. The Levin device would not function as intended (produce standing waves for thrombus destruction).

In either case, the combination of Levin and Dias would not produce the ultrasound transducer as described in the present application, particularly as now claimed.

These arguments were presented to Examiner during the 13 October 2005 interview and Examiner has orally agreed the rejection would be withdrawn. Applicants acknowledge that a new search will be required in view of a better understanding of the present teaching following the interview. Applicants respectfully submit the amended claims and a Request for Continuing Examination. If Examiner believes the prosecution of this matter may be expedited by direct communication with Applicant, or Applicant's representative of record, Examiner is invited to contact us at the address, phone and e-mail addressed below.

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